

REMARKS

Applicant has amended the claims to address the objection to the drawings, the rejection of the claims under 35 USC §101 and the rejection of the claims under 35 USC §112. Applicant respectfully submits that these rejections are now moot.

Applicant respectfully traverses the Examiner's objection to the disclosure. As is described in lines 1-20 of page 10 of the present application, the plug is removed by folding or collapsing of the disc-shaped body portion 112 of the plug. This can be accomplished by pulling on the ends of a filament that is secured to a body portion 114 that depends from the disc-shaped body portion 112. Thus, the Examiner's objection to the disclosure is flawed and should be removed.

Claims 1-7 and 9-17 stand rejected under 35 USC 102(e) as being anticipated by Sepetka. Applicant has amended the claims to more particularly define over the cited prior art.

More particularly, claim 1 recites, *inter alia*,

... a second disc-shaped body portion depending from the first body portion, **the diameter of the second body** being larger than the diameter of the first body portion and **being larger than the diameter of the lumen of the blood vessel**, wherein when the first and second body portions are inserted axially into the lumen of the blood vessel

**adjacent its severed end the wall of the lumen of the blood vessel
expands and grasps the second body portion thereof and said plug
thereby occludes blood flow through the lumen and out the severed
end of the blood vessel**

Nowhere does Sepetka teach or suggest this feature.

The apparatus in Sepetka et al. includes an expandable device 4 (fiber mesh structure) which is delivered through vessel lumen(s) to an aneurysm and expanded therein to partially fill the aneurysm. The aneurysm is reduced in size so that expandable structure supports and reinforces the body and neck of the aneurysm wall (Fig. 6). The aneurysm is reduced in size by heating the aneurysm wall (by RF energy applied thereto by the device 4) or by chemical action. A sealant may be introduced into the aneurysm to seal it.

Importantly, there are significant differences between the occlusion plug of the present invention and the prior art. First, the prior art device of Sepetka is securely located in a different part of the vascular system than the claimed plug and the prior art device of Sepetka performs different functions than the claimed occlusion plug. More particularly, the claimed plug is positioned axially in the lumen of the blood vessel adjacent its severed end and held in place by the wall of the lumen of the blood vessel grasping the occlusion plug, and operates to block the flow of blood through the vessel lumen out the severed end of the blood vessel. In contrast, the expandable device of Sepetka is inserted into an aneurysm. **The aneurysm is not part of the vessel lumen; it**

is an enlargement of the vessel that protrudes radially outward like a balloon from the wall of the vessel. Therefore, the device of Sepetka does not block the flow of blood through the lumen. In fact, if it did, the patient might die.

Second, there are significant differences regarding how the prior art Sepetka device is secured in place as compared to the claimed occlusion plug. The claimed occlusion plug includes a **large diameter second body portion that is larger than the lumen diameter in its at rest state such that when pushed into the lumen, the lumen wall expands and grasps the second body portion.** In contrast, the expandable device 4 of Sepetka is maintained at a smaller diameter than the lumen of the vessel through which it travels. After expansion, it is maintained at a size that is smaller than the neck of aneurysm. The aneurysm is shrunk in size to fit around the device. Thus, the expandable device 4 is not gripped by the walls of an expanded lumen of a blood vessel, but by shrinking of the aneurysm wall.

Because of these significant differences, Applicant respectfully submits that independent claim 1 as amended is patentable over the cited prior art. Similar arguments apply to independent claim 10.

Dependent claims 2-7, 9, and 11-17 and 19-20 are patentable over the cited prior art for those reasons advanced above with respect to independent claims 1 and 10 from which they respectively depend and for reciting additional features neither taught nor suggested by the cited prior art. For example, claim 11 is directed to a filament attached

to a third body portion depending from the second body portion, the filament causing the second body portion to collapse when pulled by a user to permit removal of the plug from the severed end of the blood vessel. Nowhere does the cited prior art teach or suggest this feature.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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